TAB 4 – SUMMARY

cleartooth™ electronics

240 SAINT PAUL STREET
SUITE 305
DENVER CO 80206
Phone: 303-733-1999
Fax: 303-733-6268

SUMMARY

Submitter's name:	Cleartooth Electronics, Inc.
Address:	240 St. Paul St., Suite 305 Denver, CO 80206
Phone:	303-733-1999
Name of contact person:	Greg Holland Regulatory Specialists, Inc 3722 Ave. Sausalito Irvine, CA 92606 Phone: 949-262-0411 fax: 949-552-2821
Date the summary was prepared:	September 15, 2003
Name of the device:	Cleartooth Digital X-Ray System
Trade or proprietary name:	Cleartooth Digital X-Ray System
Common or usual name:	Extra-oral source x-ray system
Classification name:	System, x-ray, extra-oral source, digital

The legally marketed device to which we are claiming equivalence [807.92(a)(3)]:

DXS DIGITAL X-RAY SYSTEM

Description of the device:

The Cleartooth Digital X-Ray System software processes standard dental images captured from a sensor device that is placed in a patient's mouth as if it were dental X-ray film. It provides users with a familiar personal computer moveable window interface, including pushbuttons, tool bars, pull-down menus, and pop-up menus. It allows users to access its features by point and click, and it allows them to work with images using intuitive and responsive features like orienting an image.

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Indications:

An extra-oral source x-ray system which is a host PC powered device that produces digital radiographs and is intended for dental radiographic examination and diagnosis of diseases of the teeth, jaw and supporting oral structures.

Summary of the technological characteristics of our device compared to the predicate device:

The predicate DXS Digital X-Ray System K013271 and Cleartooth Digital X-Ray System were compared in the following areas and found to have similar technological characteristics and to be equivalent.

Intended use
Indications for use
Target population
Design
Materials
Performance
Biocompatibility
Mechanical safety
Chemical safety
Anatomical sites
Where used
Standards met
Thermal safety
Radiation safety
Standards met

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 3 0 2003

Cleartooth Electronics, Inc.
% Mr. Greg Holland
Regulatory Specialist
Regulatory Specialists, Inc.
3722 Ave. Sausalito
IRVINE CA 92606

Re: K033147
Trade/Device Name: Cleartooth Digital X-Ray System
Regulation Number: 21 CFR 872.1800
Regulation Name: Extraoral source x-ray system
Regulatory Class: II
Product Code: 90 MUH
Dated: September 29, 2003
Received: October 2, 2003

Dear Mr. Holland:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K033147

Device Name: Cleartooth Digital X-Ray System

Indications For Use:

An extra-oral source x-ray system which is a host PC powered device that produces digital radiographs and is intended for dental radiographic examination and diagnosis of diseases of the teeth, jaw and supporting oral structures.

(PLEASE DO NOT WRITE BELOW THIS LINE–CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____

(Per 21 CFR 801.109) (Optional Format 1-2-96)

Nancy C. Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices

510(k) Number K033147